

REMARKS

I. Status of the claims

The Office Action of September 27, 2007 was received and reviewed. Reconsideration and withdrawal of the currently pending rejections are requested for the reasons advanced in detail below.

Filed concurrently herewith is a *Request for a Three Month Extension of Time* which extends the shortened statutory period of response to March 27, 2008. Accordingly, Applicants respectfully submit that this response is being timely filed.

Claims 1-7 were pending prior to the instant amendment. By this amendment, claims 3-6 are amended. Claims 3 and 4 are amended to correct minor grammatical issues therein. Consequently, claims 1-7 remain pending in the instant application.

With respect to the Office Action, Applicants acknowledge with appreciation the allowance of claims 3, 4 and 7.

II. Rejection of claims 1 and 2 under 35 U.S.C. § 102(a) and (e)

Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Nomura et al., U.S. 6,387,908 B1, May 14, 2002 and its application 09/508026 filed May 5, 2000 (collectively “Nomura”). This rejection is traversed for the reasons advanced in detail below.

The examiner states that Nomura teaches epoxysuccinamide derivates that can be employed in the form of physiologically acceptable salt, where the salt is an alkali meta, e.g. sodium or potassium. However, the examiner fails to show how Nomura teaches any crystalline forms of the epoxysuccinamide derivatives.

The claimed invention is not merely the potassium or sodium salt of a known compound. As recited in claims 1 and 2, Applicants’ claimed invention is the crystalline sodium salt of (2S, 3S)-3-[(1S)-1-isobutoxymethyl-3-methylbutyl]carbamoyl]oxirane-2-carboxylate and the crystalline potassium salt of (2S, 3S)-3-[(1S)-1-isobutoxymethyl-3-methylbutyl]carbamoyl]oxirane-2-carboxylate, respectively. One of ordinary skill would understand these claims to recite unique compounds and, more particularly, the crystalline forms of those unique

compound. Nothing in the prior art cited by the Examiner teaches or would have rendered Applicants' claimed invention obvious to one of ordinary skill.

While Nomura discloses compound 87, it does not disclose a crystalline sodium salt of compound 87. Example 48 in Nomura references example 23 for the procedures used to make compound 87, but example 23 explicitly states that a white amorphous product is formed. See col. 18, lines 25-29. There is no suggestion that a crystalline product is formed. The Examiner points to the generic discussion in Nomura to support the general position that salts of the compound are known. But this falls short when, as here, the claimed invention is more particular than those general teachings. Among the specific exemplary compounds disclosed in Nomura, none of them is a crystalline salt, much less a crystalline sodium salt or a crystalline potassium salt. While as general propositions salts of a free base may be formed, such general propositions would not have lead one of ordinary skill to Applicants' claimed invention.

Applicants' claimed invention is directed to the crystalline sodium salt of (2S, 3S)-3-[(1S)-1-isobutoxymethyl-3-methylbutyl]carbamoyl]oxirane-2-carboxylate and the crystalline potassium salt of (2S, 3S)-3-[(1S)-1-isobutoxymethyl-3-methylbutyl]carbamoyl]oxirane-2-carboxylate. Applicants are not merely claiming a salt of (2S, 3S)-3-[(1S)-1-isobutoxymethyl-3-methylbutyl]carbamoyl]oxirane-2-carboxylate, but crystalline salts of the compound. This is not taught in the art.

Claiming the crystalline form further distinguishes the claimed invention from the salts of compound that already are known. As disclosed in the specification, the crystalline form of (2S, 3S)-3-[(1S)-1-isobutoxymethyl-3-methylbutyl]carbamoyl]oxirane-2-carboxylate exhibits many beneficial, unexpected properties, such as low hygroscopicity and increased thermal stability. See, e.g., page 2, lines 1-8.

Applicants have further distinguished the claimed invention by its DSC thermogram and characteristic IR peaks recited in the claims. As is well known to those in the art of solid-state chemistry, these are common methods of classifying crystalline forms. The examiner has not showed where the prior-art references teach these claim elements, or why one skilled in the art would have expected a non-crystalline form of the compound to have the same DSC thermogram and IR spectrum as the claimed crystalline forms.

The compound No. 87 disclosed in Nomura et al. (in Table 1 at column 9) appears to be the same as the carboxylic acid contained in the salt defined in claims 1 and 2, as provided by the Examiner. Further, a sodium salt of the carboxylic acid (compound No. 87) appears to be disclosed in Example 48 (column 23, lines 35-49). Example 48, however, is silent with respect to crystallization of the sodium salt of the compound No. 87. Crystallization is a significant and technically important phenomenon. One skilled in the art (such as Nomura et al.) would not overlook crystallization, or the disclosure thereof, unless the omission was intentional. Accordingly, the sodium salt of the compound No. 87 should not be considered crystallized in Example 48 of Nomura et al.

On the other hand, claims 1 and 2 define crystalline sodium (claim 1) or potassium (claim 2) salts. Applicants found that the sodium or potassium salt can be crystallized according to a new process, recited in claims 3 or 4. The crystalline of the compound exhibits long storage-life, as is described in the present specification on page 2, lines 33-36. The effect of the present invention is described in the present specification on page 11, lines 14-18 and on page 12, line 36 to page 13, line 7.

A comparative stability test is also provided in Example 15 in the present specification on page 22, line 8 to page 23, line 36 which supports the effect of the present invention (a long storage-life) by comparing a crystalline compound according to the present invention with an amorphous compound disclosed in the prior art. Further, the results of IR testing defined in claims 1 and 2 of the present invention are completely different from those of the sodium salt of the compound No. 87 in Example 48 of Nomura et al.

For the reasons mentioned above, the rejection given at paragraphs 3 and 4 of the Office Action, as applied to claims 1 and 2, should be reconsidered and withdrawn.

III. Rejection of claims 5 and 6 under 35 U.S.C. § 102(a) and (e)

With regard to the rejection of claims 5 and 6 under 35 U.S.C. 102(a) and (e) given at Paragraphs 3 and 5 of the Office Action, Applicants have amended claims 5 and 6 to exclude

triethylamine and pyridine disclosed in Nomura et al. from these claims to further distinguish these claims over the cited art.

IV. Conclusion

In view of the foregoing, it is respectfully requested that the rejections of record be reconsidered and withdrawn by the Examiner, that claims 1-7 be allowed and that the application be passed to issue. If a conference would expedite prosecution of the instant application, the Examiner is hereby invited to telephone the undersigned to arrange such a conference.

Respectfully submitted,

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